



CONGRESSIONAL HEARING RESUME

106TH Congress

Date: 12 Oct 99

SUBJECT: Hearing on Defense Vaccines: Force Protection or False Security

COMMITTEE: Committee on Government Reform

CHAIRMAN: The Honorable Dan Burton

MEMBERS PRESENT:

REPUBLICANS

**Dan Burton, IN
Connie Morella, MD
Chris Shays, CT
Steven Horn, CA
Lee Terry, NE**

DEMOCRATS

**Henry Waxman, CA
Elijah Cummings, MD
Janice Schakowsky, CA**

Non committee Members attending included **Rep Jones, R-NC**

WITNESSES: See next page

Information contained in this resume was obtained during an open hearing. It will not be released outside of the Department of Defense (DOD) agencies until published hearing transcripts have been released by the Committee, and only to the extent it is in accord with published hearing procedures.

Prepared by: Maj Brad Oswalt

Date: 12 Oct 1999

Ext: 697-9110

WITNESSES

Panel One

Dr Sue Bailey
Assistant Secretary of Defense for Health Affairs

Maj Gen Randy West, USMC
Special Assistant to Secretary of Defense for
Biological Warfare and Anthrax

Lt Col Randy Randolph, USA
Director, Anthrax Vaccine Immunization Program Agency

Dr Cedric Dumont
Medical Director, State Department

Dr Kathryn Zoon
Director, Center for Biologics, Evaluation and Research,
Food and Drug Administration

Dr Chan
Director, Special Studies, General Accounting Office

Panel Two

Adm William Crowe Jr., USN Retired
Former Chairmen, Joint Chief of Staff

Dr Jack Melling
The Salk Institute

Milton Leitenberg
Center for International and Security
University of Maryland

Dr John Classen, Baltimore Maryland

Major Sonnie Bates, USAF
Pilot, Dover AFB

Major Thomas Rempfer, USAFR

Dr Neal Halsey
Director, Institute for Vaccine Safety
Johns Hopkins University

EXECUTIVE SUMMARY

The Committee continued to probe all aspects of the anthrax vaccination immunization program (AVIP). As with previous hearings, Members questioned DoD about the threat, safety, and efficacy of the vaccine, tracking methods, extent of adverse reactions, and DoD involvement with BioPort Corporation. DoD witnesses continued to voice strong support for the program's safety and efficacy and re-emphasized the threat. The State Department stated they believe the anthrax vaccine is safe and effective, although their program is voluntary. FDA re-emphasized that they believe the vaccine is safe and effective for high-risk personnel. GAO continued to question the effectiveness of the vaccine and long-term safety. An active duty pilot from Dover AFB indicated that at least 12 individuals were sick at Dover due to the vaccine. He also stated that he was threatened with court martial if he refused the vaccination and may face up to two years in prison. Retired Admiral Crowe, who is a member of the board of directors at BioPort, stated unequivocally that he never solicited any official in the Administration to install or promote the mandatory anthrax vaccination program.

The hearing opened at 1310.

Chairman Burton's Opening Remarks:

- Highlighted that the U.S. is the only country in NATO to mandate the anthrax vaccine
- Questioned how DoD can provide accurate data on adverse reactions without an active follow-up and tracking system
- Asked whether we need to look at other methods for dealing with the biological threat such as good detection equipment and protective gear

Rep Waxman:

- Indicated DoD could improve its performance, but emphasized that the risk of not vaccinating our personnel is extremely high
- Need to make decisions on critical analysis, not innuendo and personal anecdotes

Rep Shays: Compared the AVIP to a "Medical Maginot Line"

PANEL ONE

Dr Bailey: Stated there is a clear threat and reactions are generally minor

Maj Gen West:

- Has studied this issue thoroughly since taking over his current position and is more convinced than ever that the vaccine is safe and effective
- He'd be derelict in his duty if he didn't support the vaccine

Dr Zoon, FDA:

- Clinical trials support the safety of the vaccine for at-risk populations
- Commented that there have been only 425 adverse reactions reported through the Vaccine Adverse Event Reporting System (VAERS) since 1990 with only 24 considered serious
- These small figures do not warrant safety concerns by the FDA at this point

Dr Chan, GAO:

- Again questioned the requirement for a six shot regimen and indicated that a long-term study has not been done regarding safety of the vaccine
- Indicated that testing does not support claims that the anthrax vaccine will be effective against all strains of anthrax

Some key comments, questions and answers:

- Rep Waxman commented that it might be a good idea to vaccinate against anthrax even if the vaccine only protected against a portion of the 31 anthrax strains
- Rep Morella was concerned about gender differences regarding the vaccine. The FDA commented that long-term percentages of serious reactions are the same for men and women
- Rep Schakowsky asked if the DoD was concerned about the loss of Reserve and Guard pilots. Maj Gen West said we are concerned, but given the threat, he couldn't responsibly stop the program when we know the vaccine is safe and effective
- Rep Shays stated that DoD is NOT following the FDA mandated shot protocol and believes that DoD is only interested in providing three shots as opposed to the six shot series. He attributed this to DoD's belief that most protection is achieved following three vaccinations. Dr Bailey and Maj Gen West adamantly denied Rep Shay's assertions and stated that some personnel may be late for vaccinations for a host of reasons, but DoD continues to do its best to meet the FDA six-shot protocol

Panel Two**Admiral Crowe:**

- Stated rumors that decisions to initiate vaccinations in DoD were made to benefit Adm Crowe were ridiculous and he never solicited any support for the program to DoD

Major Bates:

- Says people are sick at Dover AFB and illnesses are due to the vaccine
- He's never seen the magnitude of illness that he sees at Dover
- When he expressed his concern to his SQ CC he was directed to the Area Defense Council and was told that because of his rank the AF may attempt to make an example of him through a court martial

Some key comments, questions, and answers:

- Rep Shays stated that he is leaning toward making the vaccine voluntary until DoD and BioPort "get their act together." He said that it is clear that DoD is not following the FDA mandated protocol for vaccinations and needs oversight from an outside source
- Maj Rempher, USAFR, stated he knew of a B-1 pilot in the ANG who was threatened with a \$500 fine and six months in jail for requesting a transfer due to the anthrax vaccine

The hearing was adjourned at 1730